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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,666	10/29/2001	Ben A. Bahr	UCONBA/186/US	1007
2543	7590	06/13/2005	EXAMINER	
ALIX YALE & RISTAS LLP 750 MAIN STREET SUITE 1400 HARTFORD, CT 06103			MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/056,666

**Applicant(s)**

BAHR, BEN A.

**Examiner**

Michael V. Meller

**Art Unit**

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 15-19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 9-12, 14, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The finality of the last office action is withdrawn and the case is re-opened for prosecution.

#### ***Election/Restrictions***

The restriction and election of species of record is maintained for the reasons of record.

Claims 1-8, 15-19 are withdrawn from further consideration by the examiner as being drawn to non-elected subject matter.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 9, 10, 14, 24, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Platt et al. '97 (abstract, page 429) or Platt et al. '98 (abstract, pages 427-428).

Both references each teach a lysosomal modulating compound since the N-buyldeoxynojirimycin is administered to Tay-Sachs mice. N-buyldeoxynojirimycin is considered to be a lysosomal modulating compound since it is administered to treat a lysosomal storage disorder such as tay-sachs disease.

Claims 9-12, 14, 24, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Tung et al.

Tung teaches that benzyloxycarbonyl-Phe-Phe-diazomethylketone (see claim 12) is administered to treat Alzheimer's disease in a patient, see col. 4, lines 50-55, cols. 27 and 28, example number 35, last line of the page.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11, 14, 24, 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds of claim 12, does not reasonably provide enablement for any and all lysosomal modulating compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for the compounds of claim 12, but is not enabled for any and all lysosomal modulating compounds.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all lysosomal modulating compounds. If it was so well known and clearly available, it would be clear from the prior art that such is the case, but the reverse is true.

In fact when a search was done on claim 11 by the Patent Office library, the structure was found to be so broad it was unsearchable. The library stated that it is impossible to search the embodiment of claim 11 wherein M comprises H at least partly because of the complexity caused by the claim not specifying the site on the amino acid where H is to be placed. Also, they stated that the other substituents were also impossible to place. Further, it is noted that M comprises H and thus it could include other elements too in addition to H, thus this claim is simply unsearchable.

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Applicant has only shown in their examples the six peptides of claim 12. With only the six sources of the claimed lysosomal modulating compounds it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given the six particular lysosomal modulating compounds.

Thus, the claims are unduly broad and do not find proper support from the instant specification. Thus, the rejection is properly made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'M. V. Meller', followed by a long horizontal line extending to the right.

Michael V. Meller  
Primary Examiner  
Art Unit 1654

MVM